

**REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 15-20 and 27-37 are in the case.

**I. CLAIM OBJECTIONS**

Claims 1-9, 17-20, 32-38 are objected to because of the informalities noted on pages 2 and 3 of the Action. The following comments are offered.

Claims 1-14 have been canceled without prejudice. The objections raised against those claims have accordingly been rendered moot.

The Action suggests that dependent claims be amended to read "The method of claim ..., wherein..." That suggestion has been adopted.

It is noted that claims 32 to 38 have been renumbered as 31-37. That amendment to the claim numbering is incorporated into the amended set of claims presented herewith.

The Action suggests that claim 36 (now claim 35) be amended to read, "or another marker that is an inheritable trait". That amendment has been effected.

The Action suggests amendment of claim 15(a) to read, "provides a non-inheritable trait to the host cell". That amendment has been adopted.

The suggested amendment to item (d) of claim 15 is not understood. The suggested amendment to claim 35(c) (now claim 34) has been adopted. Withdrawal of the claim objections is respectfully requested.

## **II. THE WRITTEN DESCRIPTION REJECTION**

Claims 1-9, 15-20 and 27-38 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is respectfully traversed.

In response, and without conceding to this rejection, the claims have been amended to replace the feature "at least one DNA" with "an expression cassette". Support for this feature appears in the application as filed at page 4, line 30 to page 5, line 2 and in Examples 4 and 5. No new matter is entered.

Amendment of the claims to read only on fluorescent labeling of an expression cassette clearly overcomes the written description rejection. It is clear from the originally filed description (page 4, line 30 to page 5, line 2 and Examples 4 and 5) that the inventor had possession of the invention as now claimed as of the filing date of the application. Withdrawal of the written description rejection is respectfully requested.

## **III. THE ENABLEMENT REJECTION**

Claims 1-5, 7-9 and 29-34 are rejected under 35 U.S.C. §112, first paragraph, as allegedly based on a disclosure which is not enabling. The Action alleges that the claimed methods are missing critical or essential method steps needed to practice the invention. The rejection is respectfully traversed.

Claims 1-5 and 7-9 have been canceled without prejudice. The rejection as it pertains to those claims has accordingly been rendered moot.

With regard to claims 29-34, the non-enablement rejection because the remaining claims, including claims 29-34, do comprise the required critical method steps. Withdrawal of the enablement rejection is respectfully requested.

**IV. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION**

Claims 1-5, 7-9, 15-20 and 27-38 are rejected under 35 U.S.C. §112, second paragraph, as allegedly failing to set forth the subject matter which applicant (s) regard as their invention. In response, as claims 1-9 have been canceled without prejudice, the rejection of those is rendered moot. Withdrawal of the 35 U.S.C. §112, second paragraph rejection of claims 1-9 is respectfully requested.

Referring to the rejection of claims 16, 30 and 35 as allegedly indefinite for the recitation of "under proliferating conditions", such conditions would have been readily understandable to one of ordinary skill in this art as of the filing date of the application, such as, for example, the description provided in Example 1. It is not necessary, therefore, for the claims and/or the specification to set forth what the proliferating conditions are.

Claim 15 is rejected as allegedly ambiguous. In response, the amendments to claim 15 clarify that the fluorescent label is the non-inheritable trait. The objection to claim 15(e) is not understood as there is no reference in that claim to an "experimental versus the control group" quoted in the Action.

Referring to the objection that there is no "nexus" between method step (e) and the preamble, claim 15 clearly establishes how the host cell is modified by specifying the isolation (from non-labeled progeny of the transfected host cell) a modified host cell

having a changed metabolic property as compared to the host cell prior to transfection.

The required nexus is believed to be present.

Claim 16 is rejected as indefinite for the recitation of "said DNA is involved in production of the desired metabolite". The amendment to claim 16 obviates this rejection.

Claim 20 is rejected indefinite for the recitation of an "anti-infective" as indefinite. This expression means an agent which counters infection. Reconsideration is respectfully requested.

Claim 28 is rejected as indefinite for the recitation of "wherein RNA and protein expression levels are altered in the modified host cell" as it is unclear how these are altered based on the method steps of claim 15. With the amendment to claim 15, it is believed that claim 28 is consistent with claim 15.

Withdrawal of the formal rejection is now believed to be in order. Such action is respectfully requested.

## **V. THE ANTICIPATION REJECTIONS**

Claims 1-4, 6, 8-9, 15-18, 28-30, 33-35 and 37-38 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Wolff *et al.* (U.S. Patent No. 6,262,252, July 17, 2001) (Wolff). Claims 1-4, 6, 8-9, 15-18, 28-30, 33-35 and 37-38 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Johnson *et al.* (AAPS Pharmsci, 1999, cited on the IDS filed January 18, 2007) (Johnson).

Claims 1-9 have been canceled without prejudice. The anticipation rejection is therefore rendered moot with regard to those claims.

Claim 15 provides a method for preparation of a modified host cell. The method comprises (a) transfecting a host cell with an expression cassette which is covalently coupled to a fluorescent label that provides a non-inheritable trait to the host cell, (b) isolating the transfected host cell by detecting the fluorescent label and then separating fluorescent host cells which were transfected from non-fluorescent host cells which were not transfected, (c) culturing the transfected host cell such that fluorescently-labeled polynucleotide integrates into the host cell's genome, (d) multiplying the transfected host cell which has polynucleotide integrated in its genome such that the fluorescent label is diluted and lost in progeny of the transfected host cell, and (e) isolating from non-labeled progeny of the transfected host cell a modified host cell having a changed metabolic property as compared to the host cell prior to transfection.

The claimed method requires transfection of a host cell with an expression cassette to provide a modified host cell having a changed metabolic property as compared to the host cell prior to transfection. Neither Wolff nor Johnson describes integration of a fluorescently-labeled expression cassette thereby changing a metabolic property of transfected host cells. In addition, a disclosure of a fluorescently-labeled DNA, such as a plasmid, is not a disclosure of a fluorescently-labeled expression cassette (even if such expression cassette was present in said DNA). There are relatively few fluorescent labels attached per molecule of DNA and, even if there is a theoretical chance that covalent linkage takes place at the expression cassette, this is in no way disclosed by the two cited references. Withdrawal of the anticipation rejections is respectfully requested.

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Favorable action is awaited.

Respectfully submitted,

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